IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ALLERGAN, INC., **Plaintiff,** **v.** **APOTEX INC., APOTEX CORP., SANDOZ, INC., HI-TECH PHARMACAL CO., INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.,** **Defendants.**	**Civil Action No. 1:13-cv-16** **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendants Apotex Inc. and Apotex Corp. (together "Apotex"), Sandoz, Inc. ("Sandoz"), Hi-Tech Pharmacal Co., Inc. ("Hi-Tech"), Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (together "Watson) (collectively Apotex, Sandoz, Hi-Tech, and Watson, "Defendants"), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff"), by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,263,054 ("the '054 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the '054 patent under 28 U.S.C. §§ 2201 and 2202 relating to Allergan's commercially successful hypotrichosis treatment, Latisse®.

THE PARTIES

2. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

5. On information and belief, Apotex Corp. is a subsidiary of Apotex, Inc.

6. On information and belief, Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540 and a Registered Agent, Corporation Service Company, at 327 Hillsborough Street, Raleigh, NC 27603.

7. On information and belief, Hi-Tech is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 369 Bayview Avenue, Amityville, NY 11701.

8. On information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

9. On information and belief, Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 132 Business Center Drive, Corona, CA 92880.

10. On information and belief, Watson Laboratories is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers and directors.

11. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 Campus Drive, Florham Park, New Jersey 07932.

12. On information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers and directors.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*., including §§ 271(e)(2), 271(a), 271(b), and 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

Personal Jurisdiction over Apotex

14. This Court has personal jurisdiction over Apotex by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiff and the causes of action Plaintiff has raised, as alleged herein.

15. Specifically, this Court has personal jurisdiction over Apotex Inc. and Apotex Corp. because they, either directly or through an agent, including each other, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this

jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

16. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the generic Bimatoprost Topical Solution, 0.03% described in ANDA No. 201894 (defined below).

17. Further demonstrating the close interconnections between the two entities is the fact that both Apotex Inc. and Apotex Corp. provided Plaintiff with notice, via a single letter, that the two entities had submitted a new drug application for Bimatoprost Topical Solution, 0.03% to the United States Food and Drug Administration ("FDA").

18. On information and belief, Apotex Corp. is a licensed drug wholesaler in North Carolina.

19. On information and belief, Apotex Corp. is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

20. On information and belief, an officer of Apotex Corp. has attended multiple meetings held by the North Carolina Board of Pharmacy on behalf of Apotex Corp.

21. On information and belief, Apotex Inc.'s drug products are listed on relevant North Carolina formulary(ies).

22. On information and belief, Apotex Corp. sells numerous generic drugs, manufactured and supplied by Apotex Inc., throughout the United States, including in this judicial district.

23. On information and belief, in 2009 Apotex Corp. sold over $348 million worth of Apotex Inc.'s products in North Carolina, over $51 million of which were sold in this judicial district.

24. On information and belief, Apotex Inc. has brought lawsuits in this judicial district against other drug manufacturers.

25. On information and belief, Apotex Inc. filed suit against Eisai Inc. and Eisai Co., Ltd. on July 1, 2009 in this judicial district, Case No. 1:09-CV-00477.

26. On information and belief, Apotex Inc. filed suit against Glaxo Wellcome Inc. and SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, on July 6, 2009 in this judicial district, Case No. 1:09-CV-00485.

Personal Jurisdiction over Sandoz

27. This Court has personal jurisdiction over Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiff and the causes of action Plaintiff has raised, as alleged herein.

28. Specifically, this Court has personal jurisdiction over Sandoz because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

29. On information and belief, Sandoz is a licensed drug manufacturer in North Carolina and has a manufacturing facility located at 4700 Sandoz Drive, Wilson, North Carolina 27893.

30. On information and belief, Sandoz is a licensed drug wholesaler in North Carolina.

31. On information and belief, Sandoz is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

32. On information and belief, Sandoz's drug products are listed on relevant North Carolina formulary(ies).

33. On information and belief, in 2010 Sandoz sold over $460 million of products in North Carolina, over $81 million of which were sold in this judicial district.

Personal Jurisdiction over Hi-Tech

34. This Court has personal jurisdiction over Hi-Tech by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiff and the causes of action Plaintiff has raised, as alleged herein.

35. Specifically, this Court has personal jurisdiction over Hi-Tech because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

36. On information and belief, Hi-Tech is a licensed drug manufacturer in North Carolina.

37. On information and belief, Hi-Tech is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

38. On information and belief, E. Claiborne Robinson Company, Inc., which employs pharmaceutical sales representatives in North Carolina and has an office in North Carolina, operates as a wholly owned subsidiary of Hi-Tech.

39. On information and belief, Hi-Tech's drug products are listed on relevant North Carolina formulary(ies).

40. On information and belief, in 2010 Hi-Tech sold over $19 million of products in North Carolina, over $7 million of which were sold in this judicial district.

Personal Jurisdiction over Watson

41. This Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma by virtue of their systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiff, and the causes of action Plaintiff has raised, as alleged herein.

42. Specifically, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because they, either directly or through an agent, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

43. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the generic Bimatoprost Ophthalmic Solution 0.03%, described in ANDA No. 203749 (defined below).

44. On information and belief, Watson Pharma and Watson Laboratories are licensed drug wholesalers in North Carolina.

45. On information and belief, Watson Pharma is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

46. On information and belief, Watson Pharma's drug products are listed on relevant North Carolina formulary(ies).

47. On information and belief, Watson Pharma markets and sells generic drugs manufactured by Watson Laboratories throughout the United States, including in this judicial district.

48. On information and belief, in 2011 Watson Pharma sold over $320 million of products in North Carolina, over $136 million of which were sold in this judicial district.

49. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have previously availed themselves of this forum for purposes of litigating their disputes. Specifically, on information and belief, in Case No. 1:10-CV-462, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma sought removal of a suit from state court to federal court in this judicial district (General Court of Justice, Superior Court Division, County of Guildford, North Carolina, Docket No. 10-CVS-6027).

50. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

51. On September 11, 2012, the ’054 patent, entitled “Method of Enhancing Hair Growth,” issued to David F. Woodward and Amanda M. VanDenburgh. A copy of the ’054 patent is attached to this Complaint as Exhibit A.

52. Allergan, as assignee, owns the entire right, title, and interest in the ’054 patent.

53. Allergan is the holder of an approved New Drug Application (“NDA”) No. 22-369 for bimatoprost ophthalmic solution, 0.03%, sold under the Latisse® registered trademark. In conjunction with NDA No. 22-369, Allergan listed U.S. Patent Nos. 7,351,404 (“the ’404 patent), 7,388,029 (“the ’029 patent”), 6,403,649 (“the ’649 patent”), 8,038,988 (“the ’988 patent”), 8,101,161 (“the ‘161 patent), 8,017,655 (“the ’655 patent”), and the ’054 patent with FDA as covering Latisse® or approved methods of using Latisse®.

54. Latisse® is covered by at least one claim of each of the ’404, ’029, ’649, ’988, ’161, ’655, and ’054 patents.

ACTS GIVING RISE TO THIS ACTION FOR APOTEX’S INFRINGEMENT OF THE ’054 PATENT

55. On information and belief, Apotex has submitted ANDA No. 201894 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (“FDCA”), seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Topical Solution, 0.03%, a generic version of Allergan’s Latisse® product.

56. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Apotex included with its ANDA No. 201894, a Paragraph IV certification for the ’404 and ’029 patents. Allergan received written notification of Apotex’s § 505(j)(2)(A)(vii)(IV) allegations regarding the ’404 and ’029 patents on or about July 27, 2010 (“Apotex Paragraph IV letter”).

57. Within 45 days of receiving Apotex’s Paragraph IV letter, Allergan and Duke University filed *Allergan, Inc., et al v. Apotex Inc. et al.*, C.A. 10-CV-681, asserting the ’404 and ’029 patents against Apotex.

58. The ’054 patent had not issued at the time Apotex submitted its certification under section 505(j) of the FDCA.

59. On information and belief, Apotex became aware of the ’054 patent no later than when it was listed in the Orange Book as a patent covering the approved formulation of Latisse®.

60. Apotex has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Latisse® product before the expiration of the '054 patent.

61. Apotex's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

62. On information and belief, Apotex continues to seek approval of ANDA No. 201894 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

63. On information and belief, following FDA approval of its ANDA No. 201894, Apotex will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

ACTS GIVING RISE TO THIS ACTION FOR SANDOZ'S INFRINGEMENT OF THE '054 PATENT

64. On information and belief, Sandoz has submitted ANDA No. 202719 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) ("FDCA"), seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Topical Solution, 0.03%, a generic version of Allergan's Latisse® product.

65. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Sandoz included with its ANDA No. 202719 a Paragraph IV certification for the '404 and '029 patents. Allergan received written notification of Sandoz's § 505(j)(2)(A)(vii)(IV) allegations regarding the '404 and '029 patents on or about March 3, 2011 ("Sandoz Paragraph IV letter").

66. Within 45 days of receiving Sandoz's Paragraph IV letter, Allergan and Duke University filed *Allergan, Inc. et al. v. Sandoz Inc.*, C.A. 1:11-CV-298, asserting the '404 and '029 patents against Sandoz.

67. The '054 patent had not issued at the time Sandoz submitted its certification under section 505(j) of the FDCA.

68. On information and belief, Sandoz became aware of the '054 patent no later than when it was listed in the Orange Book as a patent covering the approved formulation of Latisse®.

69. Sandoz has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Latisse® product before expiration of the '054 patent.

70. Sandoz's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

71. On information and belief, Sandoz continues to seek approval of ANDA No. 202719 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

72. On information and belief, following FDA approval of its ANDA No. 202719, Sandoz will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

ACTS GIVING RISE TO THIS ACTION FOR HI-TECH'S INFRINGEMENT OF THE '054 PATENT

73. On information and belief, Hi-Tech has submitted ANDA No. 203051 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) ("FDCA"),

seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Topical Solution, 0.03%, a generic version of Allergan's Latisse® product.

74. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Hi-Tech included with its ANDA No. 203051 a Paragraph IV certification for the '404 and '029 patents. Allergan received written notification of Hi-Tech's § 505(j)(2)(A)(vii)(IV) allegations regarding the '404 and '029 patents on or about July 5, 2011 ("Hi-Tech Paragraph IV letter").

75. Within 45 days of receiving Hi-Tech's Paragraph IV letter, Allergan and Duke University filed *Allergan, Inc. et al. v. Hi-Tech Pharmacal Co., Inc.*, C.A. 1:11-CV-650, asserting the '404 and '029 patents against Hi-Tech.

76. The '054 patent had not issued at the time Hi-Tech submitted its certification under section 505(j) of the FDCA.

77. On information and belief, Hi-Tech became aware of the '054 patent no later than when it was listed in the Orange Book as a patent covering the approved formulation of Latisse®.

78. Hi-Tech has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Latisse® product before expiration of the '054 patent.

79. Hi-Tech's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

80. On information and belief, Hi-Tech continues to seek approval of ANDA No. 203051 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

81. On information and belief, following FDA approval of its ANDA No. 203051, Hi-Tech will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

ACTS GIVING RISE TO THIS ACTION FOR WATSON'S INFRINGEMENT OF THE '054 PATENT

82. On information and belief, Watson has submitted ANDA No. 203749 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) ("FDCA"), seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Topical Solution, 0.03%, a generic version of Allergan's Latisse® product.

83. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Watson included with its ANDA No. 203749 a Paragraph IV certification for the '404, '029 and '988 patents. Allergan received written notification of Watson's § 505(j)(2)(A)(vii)(IV) allegations regarding the '404, '029 and '988 patents on or about February 29, 2012 ("Watson Paragraph IV letter").

84. Within 45 days of receiving Watson's Paragraph IV letter, Allergan and Duke University filed *Allergan, Inc. et al. v. Hi-Tech Pharmacal Co., Inc.*, C.A. 1:12-CV-321, asserting the '404, '029 and '988 patents against Watson.

85. The '054 patent had not issued at the time Watson submitted its certification under section 505(j) of the FDCA.

86. On information and belief, Watson became aware of the ’054 patent no later than when it was listed in the Orange Book as a patent covering the approved formulation of Latisse®.

87. Watson has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan’s Latisse® product before expiration of the ’054 patent.

88. Watson’s actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

89. On information and belief, Watson continues to seek approval of ANDA No. 203749 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

90. On information and belief, following FDA approval of its ANDA No. 203749, Watson will sell the approved generic version of Allergan’s Latisse® product throughout the United States, including in North Carolina.

COUNT I

(Infringement of the ’054 Patent Under 35 U.S.C. § 271(e)(2) by Apotex’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

91. Paragraphs 1 to 90 are incorporated herein as set forth above.

92. Apotex submitted ANDA No. 201894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Bimatoprost Topical Solution, 0.03% throughout the United

States. By submitting this application, Apotex has committed an act of infringement of the ’054 patent under 35 U.S.C. § 271(e)(2)(A).

93. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the ’054 patent.

94. On information and belief, Apotex became aware of the ’054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

95. On information and belief, Apotex knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively induce the actual infringement of the ’054 patent.

96. On information and belief, Apotex knew or should have known that its proposed generic Bimatoprost Topical Solution, 0.03% will be especially made or especially adapted for use in an infringement of the ’054 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively contribute to the actual infringement of the ’054 patent.

97. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s proposed generic Bimatoprost Topical Solution, 0.03% in violation of Plaintiff’s patent rights will cause harm to Plaintiff for which damages are inadequate.

COUNT II

(Declaratory Judgment of Infringement of the ’054 Patent Under 35 U.S.C. §§ 271(b) and/or 271(c) by Apotex’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

98. Paragraphs 1 to 97 are incorporated herein as set forth above.

99. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

100. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

101. Apotex has made and will continue to make, substantial preparation in the United States, including the Middle District of North Carolina, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Bimatoprost Topical Solution, 0.03%.

102. Apotex's actions, including, but not limited to, the filing of ANDA No. 201894 and engaging in litigation to manufacture, offer to sell, sell and/or import Apotex's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

103. Any commercial manufacture, use, offer for sale, and/or importation of the Apotex proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '054 patent.

104. On information and belief, Apotex became aware of the '054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

105. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Apotex will constitute contributory infringement and/or active inducement of infringement of the '054 patent.

COUNT III

(Infringement of the ’054 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

106. Paragraphs 1 to 105 are incorporated herein as set forth above.

107. Sandoz submitted ANDA No. 202719 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Bimatoprost Topical Solution, 0.03% throughout the United States. By submitting this application, Sandoz has committed an act of infringement of the ’054 patent under 35 U.S.C. § 271(e)(2)(A).

108. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the ’054 patent.

109. On information and belief, Sandoz became aware of the ’054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

110. On information and belief, Sandoz knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively induce the actual infringement of the ’054 patent.

111. On information and belief, Sandoz knew or should have known that its proposed generic Bimatoprost Topical Solution, 0.03% will be especially made or especially adapted for use in an infringement of the ’054 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for

sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively contribute to the actual infringement of the ’054 patent.

112. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed generic Bimatoprost Topical Solution, 0.03% in violation of Plaintiff’s patent rights will cause harm to Plaintiff for which damages are inadequate.

COUNT IV

(Declaratory Judgment of Infringement of the ’054 Patent Under 35 U.S.C. §§ 271(b) and/or 271(c) by Sandoz’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

113. Paragraphs 1 to 112 are incorporated herein as set forth above.

114. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

115. There is an actual case or controversy such that the Court may entertain Plaintiff’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

116. Sandoz has made and will continue to make, substantial preparation in the United States, including the Middle District of North Carolina, to manufacture, sell, offer to sell, and/or import Sandoz’s proposed generic Bimatoprost Topical Solution, 0.03%.

117. Sandoz’s actions, including, but not limited to, the filing of ANDA No. 202719 and engaging in litigation to manufacture, offer to sell, sell and/or import Sandoz’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

118. Any commercial manufacture, use, offer for sale, and/or importation of the Sandoz proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the ’054 patent.

119. On information and belief, Sandoz became aware of the ’054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

120. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Sandoz will constitute contributory infringement and/or active inducement of infringement of the ’054 patent.

COUNT V

(Infringement of the ’054 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

121. Paragraphs 1 to 120 are incorporated herein as set forth above.

122. Hi-Tech submitted ANDA No. 203051 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Bimatoprost Topical Solution, 0.03% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the ’054 patent under 35 U.S.C. § 271(e)(2)(A).

123. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech’s proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the ’054 patent.

124. On information and belief, Hi-Tech became aware of the ’054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

125. On information and belief, Hi-Tech knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively induce the actual infringement of the ’054 patent.

126. On information and belief, Hi-Tech knew or should have known that its proposed generic Bimatoprost Topical Solution, 0.03% will be especially made or especially adapted for use in an infringement of the ’054 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively contribute to the actual infringement of the ’054 patent.

127. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech’s proposed generic Bimatoprost Topical Solution, 0.03% in violation of Plaintiff’s patent rights will cause harm to Plaintiff for which damages are inadequate.

COUNT VI

(Declaratory Judgment of Infringement of the ’054 Patent Under 35 U.S.C. §§ 271(b) and/or 271(c) by Hi-Tech’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

128. Paragraphs 1 to 127 are incorporated herein as set forth above.

129. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

130. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

131. Hi-Tech has made and will continue to make, substantial preparation in the United States, including the Middle District of North Carolina, to manufacture, sell, offer to sell, and/or import Hi-Tech's proposed generic Bimatoprost Topical Solution, 0.03%.

132. Hi-Tech's actions, including, but not limited to, the filing of ANDA No. 203051 and engaging in litigation to manufacture, offer to sell, sell and/or import Hi-Tech's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

133. Any commercial manufacture, use, offer for sale, and/or importation of the Hi-Tech proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '054 patent.

134. On information and belief, Hi-Tech became aware of the '054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

135. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Hi-Tech will constitute contributory infringement and/or active inducement of infringement of the '054 patent.

COUNT VII

(Infringement of the '054 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Bimatoprost Topical Solution, 0.03%)

136. Paragraphs 1 to 135 are incorporated herein as set forth above.

137. Watson submitted ANDA No. 203749 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Bimatoprost Topical Solution, 0.03% throughout the United States. By submitting this application, Watson has committed an act of infringement of the '054 patent under 35 U.S.C. § 271(e)(2)(A).

138. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the '054 patent.

139. On information and belief, Watson became aware of the '054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

140. On information and belief, Watson knew or should have known that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively induce the actual infringement of the '054 patent.

141. On information and belief, Watson knew or should have known that its proposed generic Bimatoprost Topical Solution, 0.03% will be especially made or especially adapted for use in an infringement of the '054 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Bimatoprost Topical Solution, 0.03% will actively contribute to the actual infringement of the '054 patent.

142. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson's proposed generic Bimatoprost Topical Solution, 0.03% in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

COUNT VIII

(Declaratory Judgment of Infringement of the '054 Patent Under 35 U.S.C. §§ 271(b) and/or 271(c) by Watson's Proposed Generic Bimatoprost Topical Solution, 0.03%)

143. Paragraphs 1 to 142 are incorporated herein as set forth above.

144. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

145. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

146. Watson has made and will continue to make, substantial preparation in the United States, including the Middle District of North Carolina, to manufacture, sell, offer to sell, and/or import Watson's proposed generic Bimatoprost Topical Solution, 0.03%.

147. Watson's actions, including, but not limited to, the filing of ANDA No. 203749 and engaging in litigation to manufacture, offer to sell, sell and/or import Watson's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

148. Any commercial manufacture, use, offer for sale, and/or importation of the Watson proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '054 patent.

149. On information and belief, Watson became aware of the ’054 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

150. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Watson will constitute contributory infringement and/or active inducement of infringement of the ’054 patent.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby requests a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

a. That judgment be entered that Apotex has infringed the ’054 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 201894 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Apotex’s proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of infringement of the ’054 patent;

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Apotex’s ANDA No. 201894 shall be a date which is not earlier than the expiration date of the ’054 patent, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, its officers, agents, servants, employees, licensees, representatives, and

attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’054 patent;

d. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex’s generic product disclosed in its ANDA No. 201894 prior to the expiration of the ’054 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex’s generic product disclosed in its ANDA No. 201894 prior to the expiration of the ’054 patent, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

f. That a declaration be issued under 28 U.S.C. § 2201 that if Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the ’054 patent;

g. That judgment be entered that Sandoz has infringed the ’054 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202719 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale

within the United States, and/or importation into the United States, of Sandoz's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of infringement of the '054 patent;

h. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Sandoz's ANDA No. 202719 shall be a date which is not earlier than the expiration date of the '054 patent, as extended by any applicable period of exclusivity;

i. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '054 patent;

j. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 202719 prior to the expiration of the '054 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

k. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 202719 prior to the expiration of the '054 patent, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

l. That a declaration be issued under 28 U.S.C. § 2201 that if Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons

acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the '054 patent;

m. That judgment be entered that Hi-Tech has infringed the '054 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203051 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Hi-Tech's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of infringement of the '054 patent;

n. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Hi-Tech's ANDA No. 203051 shall be a date which is not earlier than the expiration date of the '054 patent, as extended by any applicable period of exclusivity;

o. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Hi-Tech, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '054 patent;

p. If Hi-Tech attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Hi-Tech's generic product disclosed in its ANDA No. 203051 prior to the expiration of the '054 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

q. If Hi-Tech attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Hi-Tech's generic product disclosed in its ANDA No. 203051 prior to the expiration of the '054 patent, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

r. That a declaration be issued under 28 U.S.C. § 2201 that if Hi-Tech, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the '054 patent;

s. That judgment be entered that Watson has infringed the '054 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203749 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Watson's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of infringement of the '054 patent;

t. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Watson's ANDA No. 203749 shall be a date which is not earlier than the expiration date of the '054 patent, as extended by any applicable period of exclusivity;

u. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Watson, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with

it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’054 patent;

v. If Watson attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Watson’s generic product disclosed in its ANDA No. 203749 prior to the expiration of the ’054 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

w. If Watson attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Watson’s generic product disclosed in its ANDA No. 203749 prior to the expiration of the ’054 patent, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

x. That a declaration be issued under 28 U.S.C. § 2201 that if Watson, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson’s proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the ’054 patent;

y. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys’ fees and costs;

z. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

aa. That this Court award such other and further relief as it may deem just and proper.

Dated: January 8, 2013

/s/ Larry McDevitt

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